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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,628	02/23/2004	Joseph P. Errico	F-272	8401
51640 SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090	7590 03/24/2010			
			EXAMINER	
			NEGRELLI, CHRISTINA L	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			03/24/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/784,628

**Applicant(s)**

ERRICO ET AL.

**Examiner**

CHRISTINA NEGRELLI

**Art Unit**

3733

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI.08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Interval Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/04/2010 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 5-7, and 9-11** are rejected under 35 U.S.C. 102(e) as being anticipated by Keller (US. Pub. No. 2004/0220582 A1).

Keller discloses an apparatus having first and second baseplates (see Fig.9, ref.53), the first baseplate having a first vertebral body contacting surface and first, second and third confronting surfaces angled with respect to one another, the second baseplate having a second vertebral body contacting surface and first, second and third

confronting surfaces (see Fig.4) angled with respect to one another. The apparatus further comprises at least one shaft (Fig.4, ref. 20) having a longitudinal axis and a shaft distal end having **integrally connected** a top and bottom sets of first, second and third forward surfaces (Fig.4, refs.4, 17) angled with respect to one another **separated by a wedge portion having an angled top surface, a forward surface and an angled bottom surface, the top and bottom sets of first** (see Figure 3), **second, and third forward surfaces configured to** engage the confronting surfaces (Fig.4) of the baseplates for axial rotationally aligning the baseplates with respect to the longitudinal axis of the shaft in at least two of a plurality of possible axial rotationally aligned positions (para.0040). When the apparatus is engaged to the orthopedic device during manipulation at least two of the top set of first, second and third forward surfaces of the apparatus engage at least two of the first, second and third confronting surfaces of the first baseplate and at least two of the bottom set of first, second and third forward surfaces of the apparatus engage at least two of the first, second and third confronting surfaces of the second baseplate (see Fig.9).

Keller further discloses wherein the forward surfaces (Fig.4, refs. 4, 17) are angled with respect to one another at an orientation angle that facilitates engagement of the apparatus with the device in a plurality of rotated positions with respect to the device such that possible engagement orientations approaches include at least an anterior insertion approach and at least one anterior-lateral insertion approach (para.0040).

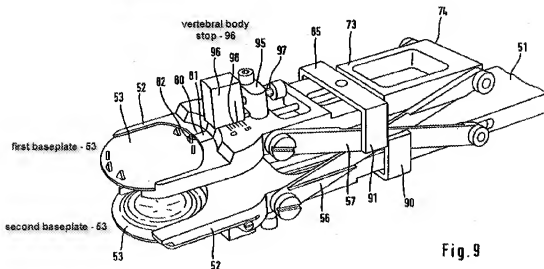
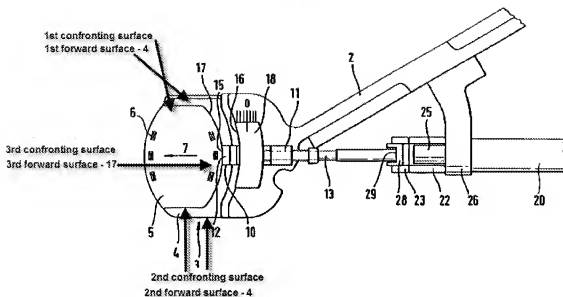
Keller further discloses wherein the forward surfaces (Fig.4, refs. 4, 17) are adapted for engagement with the device such that either an anterior-laterally facing

forward surface and an anteriorly facing forward surface is mateable with any of an anterior-laterally facing confronting surface and an anteriorly facing confronting surface.

Keller further discloses wherein the anteriorly facing forward surface (see Fig.4, ref.17) is spaced from the anteriorly facing confronting surface when two anterior-laterally facing surfaces are engaged with two anterior-laterally facing forward surfaces (see Fig.4, ref.4). This spacing is caused by a stop (see Fig.4, ref. 15) that controls the spacing of the device and the apparatus (para.0030). Keller also discloses wherein engagement of at least two of the forward surfaces (see Fig.4, ref. 4) with at least two of the confronting surfaces significantly limits movement and rotation of the at least one of the baseplates (ref. 53) relative to the apparatus (see Fig.9).

Keller further discloses a vertebral body stop (Fig.4, ref.96), wherein the stop prevents over-insertion of the device into an intervertebral space (para.0040).

**Fig. 4**



**Fig. 9**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller (US Pub. No. 2004/0220582 A1).

Keller discloses the claimed invention except for the forwarding surfaces being angled with respect to one another at an orientation angle of approximately 33.4 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the forward surfaces at an orientation angle of approximately 33.4 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

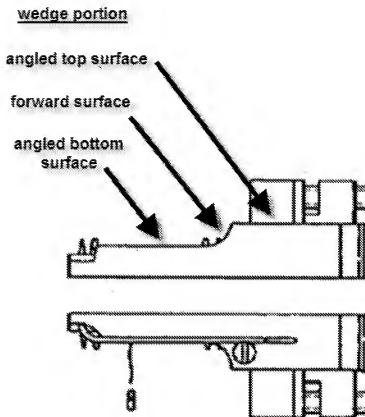
Applicant's arguments filed 01/04/2010 have been fully considered but they are not persuasive.

Independent claim 1 was amended to recite the particular configuration of the angled confronting surfaces of the baseplates of the orthopedic device corresponding to the angled forward surfaces of the apparatus for manipulating the device. Claim 1 has been amended to recite, in part, "at least one shaft having a longitudinal axis and a shaft distal end having ***integrally connected*** a top and bottom sets of first, second and third forward surfaces angled with respect to one another ***separated by a wedge portion having an angled top surface, a forward surface and an angled bottom surface, the top and bottom sets of first, second, and third forward surfaces***

**configured to** engage the confronting surfaces of the baseplates for axial rotationally aligning the baseplates with respect to the longitudinal axis of the shaft in at least two of a plurality of possible axial rotationally aligned positions.” The Applicant asserts that the Keller prior art references fails to disclose this feature. The Examiner respectfully disagrees.

Keller discloses second and third forward surfaces angled with respect to one another (as seen in Figure 4 annotated above) **separated by a wedge portion having an angled top surface, a forward surface and an angled bottom surface** (see Figure 3 annotated below), **the top and bottom sets of first, second, and third forward surfaces configured to** engage the confronting surfaces of the baseplates. The rejection of independent claim 1 and dependent claims 4-7 and 9-11 still stand supported by the Keller prior art reference.





**Fig. 3**

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA NEGRELLI whose telephone number is (571)270-7389. The examiner can normally be reached on Mon-Fri. 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. N./  
Examiner, Art Unit 3733  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733